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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,703	04/26/2001	Hermann Lubbert	STERN 1.001APC	1875

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EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,703

Applicant(s)

LUBBERT, HERMANN

Examiner

Celine X. Qian Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8, 14, 15, 22, 33, 34, 37 and 38 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 8, 14, 15, 22, 33, 34, 37 and 38 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 26 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Claims 8, 14, 15, 22, 33, 34, 37 and 38 are pending in the application.

This Office Action is in response to the Amendment filed on 8/15/05.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 8/15/05 has been entered.

Response to Amendment

The rejection of claim 14, 22, 34 and 38 under 35 U.S.C. 112 2nd paragraph has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 8, 14, 15, 22, 33, 34, 37 and 38 under 35 U.S.C. 112 1st paragraph is maintained for reasons set forth of the record mailed on 11/2/04 and further discussed below.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8, 14, 15, 22, 33, 34, 37 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to this rejection, Applicants argue that the present invention is not related to any specific phenotype, but relates to a method of making a transgenic mouse and transgenic mouse having specific recited mutations in the mouse parkin2 gene. Applicants assert that the recited mutations are in a gene from the same species as the host, thus there is a reasonable predictable outcome from the genetic disruption of the gene, a less active or inactive mouse parkin2 protein is expressed. Applicants assert that the specification teaches specific mutations of parkin2 as listed in table 1 and 2, and making a mouse with abnormal parkin2 by homologous recombination is well known in the art, which does not constitute undue experimentation.

Applicants further argue that a transgenic mouse having mutant parkin2 has already been made and the mouse showed abnormalities. Applicants thus conclude that a skill artisan will view the data as reasonable predictive of the asserted utility of the mouse. Applicants thus conclude that the claims are enabled by the instant specification.

The above arguments have been fully considered but deemed unpersuasive. For the enablement of the claimed invention, the specification has to teach not only how to make, but also how to use the claimed invention. The phenotype of the claimed mouse is critical or essential to the practice of the invention, however, they are not included in the claim(s), thus the claims are not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Without a phenotype, the claimed mouse cannot be used as an animal model for neurodegenerative diseases as taught by the instant specification. The listed mutation are mutations in human parkin2 that results in less active protein, it is unpredictable whether such

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mutation would result in same loss of function for the mouse parkin2. Further, it is unpredictable what each of these mutations would result in any phenotype such that the mouse can be used as a model for neurodegenerative disease. The parkin2 knockout mouse having a deletion in Exon 3 disclosed in the Declaration exhibits phenotypes that do not resemble symptoms of any neurodegenerative disease. Since the dopamine neurons appear to be normal in the homozygous parkin2 knockout mouse (see exhibit 3), it certainly cannot serve as an animal model for Parkinson's disease. The statement "the claimed parkin2 mouse is useful in investigating the role of parkin2 gene disruption on various types of animal behavior" is an invitation for further research on the role of parkin2 which Applicants apparently do not know. As such, without teaching from the specification, one skilled in the art would have to engage in undue experimentation to use the claimed invention. Since the claimed mouse is not enabled, the method of making said mouse is also not enabled. Therefore, this rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELIAN QIAN
PATENT EXAMINER

